

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

BARBARA GRZANECKI,)	
)	
Plaintiff,)	
)	
v.)	
)	Case No. 18-cv-00204
SMITH AND NEPHEW, INC., a Delaware)	
Corporation, ZIMMER US, INC., a Delaware)	Judge Hon. John J. Tharp
Corporation, and ZIMMER, INC., a Delaware)	
Corporation,)	
)	
Defendants.)	

AMENDED COMPLAINT AT LAW

NOW COMES Plaintiff, BARBARA GRZANECKI, by and through her attorneys, LUCAS AND CARDENAS, P.C., complains of Defendants, SMITH AND NEPHEW, INC., a Delaware Corporation, ZIMMER US, INC., a Delaware Corporation, and ZIMMER, INC., a Delaware Corporation, and alleges as follows:

FACTS COMMON TO ALL COUNTS

1. On December 3, 2015, the plaintiff, Barbara Grzanecki underwent a right total knee replacement (hereinafter “TKR”).
2. On and before December 3, 2015, Smith and Nephew, Inc., was a corporation incorporated under the laws of the State of Delaware, with its principal place of business located in the City of Memphis, County of Shelby, State of Tennessee, and was licensed to do business, and is doing business in the State of Illinois.
3. On and before December 3, 2015, Zimmer US, Inc., was a corporation incorporated under the laws of the State of Delaware, with its principal place of business located

in the City of Warsaw, County of Kosciusko, State of Indiana, and was licensed to do business, and is doing business in the State of Illinois.

4. On and before December 3, 2015, Zimmer, Inc., was a corporation incorporated under the laws of the State of Delaware, with its principal place of business located in the City of Warsaw, County of Kosciusko, State of Indiana, and was licensed to do business, and is doing business in the State of Illinois.

5. Defendant, Smith and Nephew, Inc., was and is engaged in the business of selling implants in Cook County, Illinois.

6. Defendant, Zimmer US, Inc., was and is engaged in the business of selling implants in Cook County, Illinois.

7. Defendant, Zimmer, Inc., was and is engaged in the business of selling implants in Cook County, Illinois.

8. On and before December 3, 2015, Smith and Nephew, Inc., has transacted business in Illinois and has received substantial revenue from joint replacement and other orthopedic products sold to Illinois residents.

9. On and before December 3, 2015, Zimmer US, Inc., has transacted business in Illinois and has received substantial revenue from joint replacement and other orthopedic products sold to Illinois residents.

10. On and before December 3, 2015, Zimmer, Inc., has transacted business in Illinois and has received substantial revenue from joint replacement and other orthopedic products sold to Illinois residents.

11. On and before December 3, 2015, Smith and Nephew, Inc., was in the business of specifying, designing, manufacturing, testing or selling surgical implants for the orthopedic and knee replacement markets.

12. On and before December 3, 2015, Zimmer US, Inc., was in the business of specifying, designing, manufacturing, testing or selling surgical implants for the orthopedic and knee replacement markets.

13. On and before December 3, 2015, Zimmer, Inc., was in the business of specifying, designing, manufacturing, testing or selling surgical implants for the orthopedic and knee replacement markets.

14. The implants used were Smith and Nephew, Inc., products: GNS II CMT TIB SIZE 6 RIGHT –LOG225299, LEGION PS OXIN FEM SZ6 RT – LOG225299, PATELLA IMPLANT 9X32 MM RESURFACING LAST ORDER OCT 2009 – LOG225299, LGN PS HIGH FLEX XLPE SZ5-6 13MM – LOG225299.

15. These aforementioned products were sold by Smith and Nephew, Inc.

16. The implant used were Zimmer US, Inc., product: CEMENT BONE GENTAMICIN PALACOS R+G.

17. These aforementioned product was sold by Zimmer US, Inc.

18. The implant used were Zimmer, Inc., product: CEMENT BONE GENTAMICIN PALACOS R+G.

19. These aforementioned product was sold by Zimmer, Inc.

20. The design of the implant products, the selection of the materials from which they were fabricated, the manufacturing procedures by which it was made and the inspection

procedures attendant on the manufacturer were all functions solely within the control of the Defendant, Smith and Nephew, Inc.

21. The design of the implant products, the selection of the materials from which they were fabricated, the manufacturing procedures by which it was made and the inspection procedures attendant on the manufacturer were all functions solely within the control of the Defendant, Zimmer US, Inc.

22. The design of the implant products, the selection of the materials from which they were fabricated, the manufacturing procedures by which it was made and the inspection procedures attendant on the manufacturer were all functions solely within the control of the Defendant, Zimmer, Inc.

23. Defendant, Smith and Nephew, Inc., expected the implants to reach the consumer in the condition in which it was sold.

24. Defendant, Zimmer US, Inc., expected the implants to reach the consumer in the condition in which it was sold.

25. Defendant, Zimmer, Inc., expected the implants to reach the consumer in the condition in which it was sold.

26. The implants did not undergo any substantial change after it left the manufacturer, Defendant, Smith and Nephew, Inc.

27. The implants did not undergo any substantial change after it left the manufacturer, Defendant, Zimmer US, Inc.

28. The implants did not undergo any substantial change after it left the manufacturer, Defendant, Zimmer, Inc.

29. From the date of the implant, December 3, 2015 to the present date, December 7, 2017, plaintiff used the implants in the manner for which it was intended, namely, her activities of daily living.

30. In 2016, plaintiff began experiencing pain that was not consistent with TKR.

31. In late 2016 and early 2017, scans revealed lucency and particle disease in plaintiff's right knee.

32. The aforementioned scans indicate the premature and defective failure of the implants.

33. The plaintiff was not aware of the implants defective condition until late 2016 or early 2017 when the scan were taken.

34. Defendant, Smith and Nephew, Inc., sold the implants in a defective condition which caused the implants to fail.

35. Defendant, Zimmer US, Inc., sold the implant in a defective condition which caused the implants to fail.

36. Defendant, Zimmer, Inc., sold the implant in a defective condition which caused the implants to fail.

COUNT I
STRICT PRODUCTS LIABILITY v. SMITH AND NEPHEW, INC.

1-36. Plaintiff realleges and incorporates by reference paragraphs 1 through 36 of Facts Common to All Counts, as if fully set forth in Count I.

37. This condition was unreasonably dangerous to Plaintiff, the intended user.

38. Defendant knew or had reason to know of the issues related to the failure of the product before the date that Plaintiff was implanted with the device.

39. At the time of selling, distributing and supplying the implants, the implants were unsafe and defective in that they were causing lucency and particles while being used for its intended purpose.

40. At all times relevant, the subject products were defective and unreasonably dangerous because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to the manufacturer.

41. At all times relevant, the subject products as so manufactured, fabricated, and assembled, were unreasonably dangerous to anyone who might use it for the purposes for which they were intended and it was, in fact, defective, dangerous and unsuitable to be placed in the plaintiff's body.

42. At the time the defective product left the Defendant's possession and the time the defective product entered the stream of commerce, the defective product was in an unreasonably dangerous and defective condition. These defects include but are not limited to the following:

- a. The defective product was not reasonably safe as intended to be used;
- b. The defective product had an inadequate design for its purposes;
- c. The defective product contained unreasonably dangerous design defects, including an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure;
- d. The defective product's unstable and defective design resulted in lucency and particles which had risks that exceeded the benefits of the medical device;
- e. The defective product's unstable and defective design resulted in lucency and particles which was more dangerous than the ordinary consumer would expect;
- f. The defective product failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected the Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person;
- g. The defective product was insufficiently tested;

- h. The warning to Plaintiff and Plaintiff's implanting physicians about the dangers the defective product posed to consumers, including Plaintiff, were inadequate. The inadequacy of Defendant's warnings include, but are not limited to, the following:
 - i. Insufficient to alert Plaintiff and Plaintiff's physicians as to the risk of adverse events and/or reactions associated with the defective product, subjecting Plaintiff to risks which exceeded the benefits of the defective product;
 - ii. Contained misleading warnings emphasizing the efficacy of the defective product while downplaying the risks associated with it, thereby making use of the defective product more dangerous than the ordinary consumer would expect;
 - iii. Contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the defective product;
 - iv. Did not disclose that it was inadequately tested;
 - v. Failed to convey adequate post-marketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the defective product;
 - vi. Failed to contain instructions sufficient to alert consumers to the dangers they posed, and to give them the information necessary to avoid or mitigate those dangers;
 - vii. Failure to notify individuals who had been implanted with this defective device, including Plaintiff, that the device was dangerous and may cause severe injury, thereby depriving Plaintiff of the opportunity to seek treatment avoid further injury.

43. Defendant as designer, manufacturer, marketer, and distributor of medical devices are held to the level of knowledge of an expert in their field.

44. Plaintiff and the implanting physician did not have substantially the same knowledge as the designer, manufacturer, or distributor.

45. As a direct and proximate result of the dangerous and defective condition on the implants, plaintiff has been subjected to an unreasonable risk of harm beyond that which would

be contemplated by an ordinary person with ordinary knowledge common to community as to the implants characteristics.

46. As a direct and proximate result of the defendant's products failure, the plaintiff will need to undergo revision surgery, she has suffered multiple injuries on and about her body, both internally and externally, all or some of which are permanent; that plaintiff has suffered and will suffer in the future great pain and mental anguish, and has become and will in the future be obligated for large sums of money in reasonable medical expenses in endeavoring to be treated for said injuries; that plaintiff has been unable to follow his usual occupation thereby losing large sums of money she would have otherwise earned; that plaintiff has and will continue to suffer great pain, suffering and disability.

WHEREFORE, Plaintiff, BARBARA GRZANECKI, demands judgment be entered against SMITH AND NEPHEW, INC., in an amount in excess of \$50,000.00, plus the costs of this lawsuit.

COUNT II
STRICT PRODUCTS LIABILITY v. ZIMMER US, INC.

1-36. Plaintiff realleges and incorporates by reference paragraphs 1 through 36 of Facts Common to All Counts, as if fully set forth in Count II.

37. This condition was unreasonably dangerous to Plaintiff, the intended user.

38. Defendant knew or had reason to know of the issues related to the failure of the product before the date that Plaintiff was implanted with the device.

39. At the time of selling, distributing and supplying the implant, the implants were unsafe and defective in that they were causing lucency and particles while being used for its intended purpose.

40. At all times relevant, the subject products were defective and unreasonably dangerous because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to the manufacturer.

41. At all times relevant, the subject products as so manufactured, fabricated, and assembled, were unreasonably dangerous to anyone who might use it for the purposes for which they were intended and it was, in fact, defective, dangerous and unsuitable to be placed in the plaintiff's body.

42. At the time the defective product left the Defendant's possession and the time the defective product entered the stream of commerce, the defective product was in an unreasonably dangerous and defective condition. These defects include but are not limited to the following:

- a. The defective product was not reasonably safe as intended to be used;
- b. The defective product had an inadequate design for its purposes;
- c. The defective product contained unreasonably dangerous design defects, including an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure;
- d. The defective product's unstable and defective design resulted in lucency and particles which had risks that exceeded the benefits of the medical device;
- e. The defective product's unstable and defective design resulted in lucency and particles which was more dangerous than the ordinary consumer would expect;
- f. The defective product failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected the Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person;
- g. The defective product was insufficiently tested;
- h. The warning to Plaintiff and Plaintiff's implanting physicians about the dangers the defective product posed to consumers, including Plaintiff, were inadequate. The inadequacy of Defendant's warnings include, but are not limited to, the following:

- i. Insufficient to alert Plaintiff and Plaintiff's physicians as to the risk of adverse events and/or reactions associated with the defective product, subjecting Plaintiff to risks which exceeded the benefits of the defective product;
- ii. Contained misleading warnings emphasizing the efficacy of the defective product while downplaying the risks associated with it, thereby making use of the defective product more dangerous than the ordinary consumer would expect;
- iii. Contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the defective product;
- iv. Did not disclose that it was inadequately tested;
- v. Failed to convey adequate post-marketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the defective product;
- vi. Failed to contain instructions sufficient to alert consumers to the dangers they posed, and to give them the information necessary to avoid or mitigate those dangers;
- vii. Failure to notify individuals who had been implanted with this defective device, including Plaintiff, that the device was dangerous and may cause severe injury, thereby depriving Plaintiff of the opportunity to seek treatment avoid further injury.

43. Defendant as designer, manufacturer, marketer, and distributor of medical devices are held to the level of knowledge of an expert in their field.

44. Plaintiff and the implanting physician did not have substantially the same knowledge as the designer, manufacturer, or distributor.

45. As a direct and proximate result of the dangerous and defective condition on the implants, plaintiff has been subjected to an unreasonable risk of harm beyond that which would be contemplated by an ordinary person with ordinary knowledge common to community as to the implants characteristics.

46. As a direct and proximate result of the defendant's products failure, the plaintiff will need to undergo revision surgery, she has suffered multiple injuries on and about her body, both internally and externally, all or some of which are permanent; that plaintiff has suffered and will suffer in the future great pain and mental anguish, and has become and will in the future be obligated for large sums of money in reasonable medical expenses in endeavoring to be treated for said injuries; that plaintiff has been unable to follow his usual occupation thereby losing large sums of money she would have otherwise earned; that plaintiff has and will continue to suffer great pain, suffering and disability.

WHEREFORE, Plaintiff, BARBARA GRZANECKI, demands judgment be entered against ZIMMER US, INC., in an amount in excess of \$50,000.00, plus the costs of this lawsuit.

COUNT III
STRICT PRODUCTS LIABILITY v. ZIMMER, INC.

1-36. Plaintiff realleges and incorporates by reference paragraphs 1 through 36 of Facts Common to All Counts, as if fully set forth in Count III.

37. This condition was unreasonably dangerous to Plaintiff, the intended user.

38. Defendant knew or had reason to know of the issues related to the failure of the product before the date that Plaintiff was implanted with the device.

39. At the time of selling, distributing and supplying the implant, the implants were unsafe and defective in that they were causing lucency and particles while being used for its intended purpose.

40. At all times relevant, the subject products were defective and unreasonably dangerous because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to the manufacturer.

41. At all times relevant, the subject products as so manufactured, fabricated, and assembled, were unreasonably dangerous to anyone who might use it for the purposes for which they were intended and it was, in fact, defective, dangerous and unsuitable to be placed in the plaintiff's body.

42. At the time the defective product left the Defendant's possession and the time the defective product entered the stream of commerce, the defective product was in an unreasonably dangerous and defective condition. These defects include but are not limited to the following:

- a. The defective product was not reasonably safe as intended to be used;
- b. The defective product had an inadequate design for its purposes;
- c. The defective product contained unreasonably dangerous design defects, including an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure;
- d. The defective product's unstable and defective design resulted in lucency and particles which had risks that exceeded the benefits of the medical device;
- e. The defective product's unstable and defective design resulted in lucency and particles which was more dangerous than the ordinary consumer would expect;
- f. The defective product failed to perform in a manner reasonably expected in light of its nature and intended function, and subjected the Plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person;
- g. The defective product was insufficiently tested;
- h. The warning to Plaintiff and Plaintiff's implanting physicians about the dangers the defective product posed to consumers, including Plaintiff, were inadequate. The inadequacy of Defendant's warnings include, but are not limited to, the following:
 - i. Insufficient to alert Plaintiff and Plaintiff's physicians as to the risk of adverse events and/or reactions associated with the defective product, subjecting Plaintiff to risks which exceeded the benefits of the defective product;
 - ii. Contained misleading warnings emphasizing the efficacy of the defective product while downplaying the risks associated with it, thereby making

use of the defective product more dangerous than the ordinary consumer would expect;

- iii. Contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the defective product;
- iv. Did not disclose that it was inadequately tested;
- v. Failed to convey adequate post-marketing warnings regarding the risk, severity, scope, and/or duration of the dangers posed by the defective product;
- vi. Failed to contain instructions sufficient to alert consumers to the dangers they posed, and to give them the information necessary to avoid or mitigate those dangers;
- vii. Failure to notify individuals who had been implanted with this defective device, including Plaintiff, that the device was dangerous and may cause severe injury, thereby depriving Plaintiff of the opportunity to seek treatment avoid further injury.

43. Defendant as designer, manufacturer, marketer, and distributor of medical devices are held to the level of knowledge of an expert in their field.

44. Plaintiff and the implanting physician did not have substantially the same knowledge as the designer, manufacturer, or distributor.

45. As a direct and proximate result of the dangerous and defective condition on the implants, plaintiff has been subjected to an unreasonable risk of harm beyond that which would be contemplated by an ordinary person with ordinary knowledge common to community as to the implants characteristics.

46. As a direct and proximate result of the defendant's products failure, the plaintiff will need to undergo revision surgery, she has suffered multiple injuries on and about her body, both internally and externally, all or some of which are permanent; that plaintiff has suffered and will suffer in the future great pain and mental anguish, and has become and will in the future be

obligated for large sums of money in reasonable medical expenses in endeavoring to be treated for said injuries; that plaintiff has been unable to follow his usual occupation thereby losing large sums of money she would have otherwise earned; that plaintiff has and will continue to suffer great pain, suffering and disability.

WHEREFORE, Plaintiff, BARBARA GRZANECKI, demands judgment be entered against ZIMMER, INC., in an amount in excess of \$50,000.00, plus the costs of this lawsuit.

COUNT IV
NEGLIGENCE v. SMITH AND NEPHEW, INC.

1-36. Plaintiff realleges and incorporates by reference paragraphs 1 through 36 of Facts Common to All Counts, as if fully set forth in Count IV.

37. This condition was unreasonably dangerous to Plaintiff, the intended user.

38. Defendant knew or had reason to know of the issues related to the failure of the product before the date that Plaintiff was implanted with the device.

39. At the time of selling, distributing and supplying the implants, the implants were unsafe and defective in that they were causing lucency and particles while being used for its intended purpose.

40. At all times relevant, the subject products were defective and unreasonably dangerous because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to the manufacturer.

41. At all times relevant, the subject products as so manufactured, fabricated, and assembled, were unreasonably dangerous to anyone who might use it for the purposes for which they were intended and it was, in fact, defective, dangerous and unsuitable to be placed in the plaintiff's body.

42. On, before, and after December 3, 2015, and at the time the subject products left the control of Defendant, Smith and Nephew, Inc., the defendant was negligent in one or more of the following ways:

- a. The advertising and marketing campaigns undertaken by the defendant misled consumers as to their efficacy, proper function and safety; and failed to warn consumers of the dangerous conditions of the subject products;
- b. The products were designed and manufactured in such a way to create the risk of particle disease;
- c. The products were not manufactured in compliance with good manufacturing practices;
- d. The products failed to contain adequate labeling for uses to which defendant knew, or should have known, the subject products were being put;
- e. The products were manufactured without appropriate procedures to control the design of the products to ensure that specified design requirements were met;
- f. The products were manufactured without appropriate procedures for quality audits, or the defendants failed to appropriately conduct such audits;
- g. The products were manufactured without adequate control or monitoring of production processes to ensure that the subject processes conformed to the specifications;
- h. The products were manufactured without timely review, evaluation and process revalidation after process deviations occurred; and
- i. Failed to warn about the subject products high failure rate when they knew, or should have known, warnings were necessary.

43. Defendant knew or had reason to know that Plaintiff, as a member of the general public for whose use the defective product was placed into interstate commerce, would be likely to use the defective product in a manner described in this Complaint.

44. Defendant knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the defective product, which danger would not be obvious to the general public.

45. As a direct and proximate result of the dangerous and defective condition on the implants, plaintiff has been subjected to an unreasonable risk of harm beyond that which would be contemplated by an ordinary person with ordinary knowledge common to community as to the implants characteristics.

46. As a direct and proximate result of the defendant's products failure, the plaintiff will need to undergo revision surgery, she has suffered multiple injuries on and about her body, both internally and externally, all or some of which are permanent; that plaintiff has suffered and will suffer in the future great pain and mental anguish, and has become and will in the future be obligated for large sums of money in reasonable medical expenses in endeavoring to be treated for said injuries; that plaintiff has been unable to follow his usual occupation thereby losing large sums of money she would have otherwise earned; that plaintiff has and will continue to suffer great pain, suffering and disability.

WHEREFORE, Plaintiff, BARBARA GRZANECKI, demands judgment be entered against SMITH AND NEPHEW, INC., in an amount in excess of \$50,000.00, plus the costs of this lawsuit.

COUNT V
NEGLIGENCE v. ZIMMER US, INC.

1-36. Plaintiff realleges and incorporates by reference paragraphs 1 through 36 of Facts Common to All Counts, as if fully set forth in Count V.

37. This condition was unreasonably dangerous to Plaintiff, the intended user.

38. Defendant knew or had reason to know of the issues related to the failure of the product before the date that Plaintiff was implanted with the device.

39. At the time of selling, distributing and supplying the implant, the implants were unsafe and defective in that they were causing lucency and particles while being used for its intended purpose.

40. At all times relevant, the subject products were defective and unreasonably dangerous because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to the manufacturer.

41. At all times relevant, the subject products as so manufactured, fabricated, and assembled, were unreasonably dangerous to anyone who might use it for the purposes for which they were intended and it was, in fact, defective, dangerous and unsuitable to be placed in the plaintiff's body.

42. On, before, and after December 3, 2015, and at the time the subject products left the control of Defendant, Zimmer US, Inc., the defendant was negligent in one or more of the following ways:

- a. The advertising and marketing campaigns undertaken by the defendant misled consumers as to their efficacy, proper function and safety; and failed to warn consumers of the dangerous conditions of the subject products;
- b. The products were designed and manufactured in such a way to create the risk of particle disease;
- c. The products were not manufactured in compliance with good manufacturing practices;
- d. The products failed to contain adequate labeling for uses to which defendant knew, or should have known, the subject products were being put;
- e. The products were manufactured without appropriate procedures to control the design of the products to ensure that specified design requirements were met;
- f. The products were manufactured without appropriate procedures for quality audits, or the defendants failed to appropriately conduct such audits;

- g. The products were manufactured without adequate control or monitoring of production processes to ensure that the subject processes conformed to the specifications;
- h. The products were manufactured without timely review, evaluation and process revalidation after process deviations occurred; and
- i. Failed to warn about the subject products high failure rate when they knew, or should have known, warnings were necessary.

43. Defendant knew or had reason to know that Plaintiff, as a member of the general public for whose use the defective product was placed into interstate commerce, would be likely to use the defective product in a manner described in this Complaint.

44. Defendant knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the defective product, which danger would not be obvious to the general public.

45. As a direct and proximate result of the dangerous and defective condition on the implants, plaintiff has been subjected to an unreasonable risk of harm beyond that which would be contemplated by an ordinary person with ordinary knowledge common to community as to the implants characteristics.

46. As a direct and proximate result of the defendant's products failure, the plaintiff will need to undergo revision surgery, she has suffered multiple injuries on and about her body, both internally and externally, all or some of which are permanent; that plaintiff has suffered and will suffer in the future great pain and mental anguish, and has become and will in the future be obligated for large sums of money in reasonable medical expenses in endeavoring to be treated for said injuries; that plaintiff has been unable to follow his usual occupation thereby losing large sums of money she would have otherwise earned; that plaintiff has and will continue to suffer great pain, suffering and disability.

WHEREFORE, Plaintiff, BARBARA GRZANECKI, demands judgment be entered against ZIMMER US, INC., in an amount in excess of \$50,000.00, plus the costs of this lawsuit.

COUNT VI
NEGLIGENCE v. ZIMMER, INC.

1-36. Plaintiff realleges and incorporates by reference paragraphs 1 through 36 of Facts Common to All Counts, as if fully set forth in Count VI.

37. This condition was unreasonably dangerous to Plaintiff, the intended user.

38. Defendant knew or had reason to know of the issues related to the failure of the product before the date that Plaintiff was implanted with the device.

39. At the time of selling, distributing and supplying the implant, the implants were unsafe and defective in that they were causing lucency and particles while being used for its intended purpose.

40. At all times relevant, the subject products were defective and unreasonably dangerous because they failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to the manufacturer.

41. At all times relevant, the subject products as so manufactured, fabricated, and assembled, were unreasonably dangerous to anyone who might use it for the purposes for which they were intended and it was, in fact, defective, dangerous and unsuitable to be placed in the plaintiff's body.

42. On, before, and after December 3, 2015, and at the time the subject products left the control of Defendant, Zimmer, Inc., the defendant was negligent in one or more of the following ways:

- a. The advertising and marketing campaigns undertaken by the defendant misled consumers as to their efficacy, proper function and safety; and failed to warn consumers of the dangerous conditions of the subject products;

- b. The products were designed and manufactured in such a way to create the risk of particle disease;
 - c. The products were not manufactured in compliance with good manufacturing practices;
 - d. The products failed to contain adequate labeling for uses to which defendant knew, or should have known, the subject products were being put;
 - e. The products were manufactured without appropriate procedures to control the design of the products to ensure that specified design requirements were met;
 - f. The products were manufactured without appropriate procedures for quality audits, or the defendants failed to appropriately conduct such audits;
 - g. The products were manufactured without adequate control or monitoring of production processes to ensure that the subject processes conformed to the specifications;
 - h. The products were manufactured without timely review, evaluation and process revalidation after process deviations occurred; and
 - i. Failed to warn about the subject products high failure rate when they knew, or should have known, warnings were necessary.
43. Defendant knew or had reason to know that Plaintiff, as a member of the general public for whose use the defective product was placed into interstate commerce, would be likely to use the defective product in a manner described in this Complaint.
44. Defendant knew or reasonably should have known of the danger associated with the manner and circumstances of Plaintiff's foreseeable use of the defective product, which danger would not be obvious to the general public.
45. As a direct and proximate result of the dangerous and defective condition on the implants, plaintiff has been subjected to an unreasonable risk of harm beyond that which would be contemplated by an ordinary person with ordinary knowledge common to community as to the implants characteristics.

46. As a direct and proximate result of the defendant's products failure, the plaintiff will need to undergo revision surgery, she has suffered multiple injuries on and about her body, both internally and externally, all or some of which are permanent; that plaintiff has suffered and will suffer in the future great pain and mental anguish, and has become and will in the future be obligated for large sums of money in reasonable medical expenses in endeavoring to be treated for said injuries; that plaintiff has been unable to follow his usual occupation thereby losing large sums of money she would have otherwise earned; that plaintiff has and will continue to suffer great pain, suffering and disability.

WHEREFORE, Plaintiff, BARBARA GRZANECKI, demands judgment be entered against ZIMMER, INC., in an amount in excess of \$50,000.00, plus the costs of this lawsuit.

Respectfully Submitted,
BARBARA GRZANECKI, Plaintiff



By: _____
One of Her Attorneys

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